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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,352	11/08/2000	Joan D. Leonard	02108.0001U2	1597

7590 06/18/2002

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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	12

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

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Office Action Summary	Application No.	Applicant(s)	
	09/708,352	LEONARD ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *13-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

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FINAL ACTION

1. This Office Action is responsive to Applicant's response in paper No. 10 to the first Office Action in paper No. 8. Claim 21 has been added.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

3. In view of Applicant's amendment the Rejection of claims 5-12 under U.S.C. 112, first paragraph, pages 3-6, paragraph 8 of the previous Office action is withdrawn.

4. The rejection of claims 1-4 and newly submitted claim 21 under U.S.C. 102(b) as being anticipated by Howard et al is maintained for the reasons set forth in paper 8, pages 7-8, paragraph 3 of the previous Office action.

The rejection was on the grounds that Howard et al disclose a quadrivalent vaccine containing the killed antigens of respiratory syncytial virus, parainfluenza virus type 3, *Mycoplasma bovis* and *Mycoplasma dispar* (see the Abstract). Howard et al disclose that the vaccines were formulated by suspending the antigens in phosphate buffered saline containing Quil A (Superfos) and 1% methiolate (see page 373). Characteristics such as the concentration of cells use in vaccines would be inherent in the vaccines of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's vaccine with vaccine of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the products of the prior art (i.e., that the vaccine of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The Applicant urges that Howard et al do not anticipate the claimed invention because there is no clear teaching that the vaccine of Howard et al provides

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protection against *M. bovis* clinical disease. Applicant also urges that the vaccine of Howard et al does not have the characteristics of the claimed product, namely, a protective effect against *M. bovis* clinical disease.

Applicant's arguments filed March 21, 2002 in paper No. 10 have been fully considered but are not persuasive. The applicant's arguments are not commensurate in scope with the claimed invention. The applicant is arguing limitations that are not in the claimed invention. The claimed invention is drawn to an vaccine which is protective against *Mycoplasma bovis* clinical disease in a bovine species comprising at least on inactivated or attenuated *Mycoplasma bovis* biotype and a pharmaceutically acceptable excipent. It is the Examiner's position that there is nothing on the record to show that the claimed vaccine composition is not the same as the vaccine composition of the prior art. Howard et al teach a vaccine that comprises *M. bovis*, phosphate buffered saline, Ouil A (superfos) and 1% methiolate (page 373). Howard et al teach that the quadrivalent vaccine provided protection against batch 85/1 which was associated primarily with *M. bovis* infection. Howard also teach that *M. bovis* appeared to be a major component of the disease in batch 84/5 and a higher level of protection against disease was achieved by the quadrivalent vaccine. Howard el al further teach that the *M. bovis* component of the quadrivalent vaccine protected in the field trials (page 376, 1st column). The Applicant has provided no side-by-side comparison to show that the vaccine composition of the prior art is not the same as the claimed vaccine composition.

Applicant urges that new claim 21 directed to vaccines protective against *M. bovis* mastitis is clearly not anticipated by the vaccine of Howard et al which only

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alleged to be protective against respiratory infection and not other types of *M. bovis* disease. Applicant also asserts that Heller et al, (1993) state " to control the spread of this disease an early detection of the pathogen is crucial since removal and culling of infected cows is necessary to prevent fresh infections" and further asserts that Bovine Veterinarian, (2001) disclose methods and practices to both prevent and treat the spread of the disease. The Examiner agrees that newly submitted claim 21 is directed to a vaccine which protect against *M. bovis* mastitis and Heller et al, (1993) and *Bovine Veterinarian*, (2001) provide support for vaccines protecting against bovine mastitis. However, claim 21 is drawn to a vaccine that comprises at least one *M. bovis* biotype. The claimed vaccine is a product and limitations such as "protective against *Mycoplasma bovis* mastitis in a bovine species following systemic administration" are viewed as inherent.

5. The rejection of claims 5-12 and newly submitted claim 21 under U.S.C. 103(a) as being anticipated by Howard et al in view of Poumarat et al is maintained for the reasons set forth in paper 8, pages 8-9, paragraph 4 of the previous Office action.

The rejection was on the grounds that Howard et al disclose a quadrivalent vaccine containing the killed antigens of respiratory syncytial virus, parainfluenza virus type 3, *Mycoplasma bovis* and *Mycoplasma dispar* (see the Abstract). Howard et al disclose that the vaccine was formulated by suspending the antigens in phosphate buffered saline containing Quil A (Superfos) and 1% methiolate (see page 373).

Howard et al does not teach a biotype A, B, C *Mycoplasma bovis*.

Poumarat et al disclose Restriction endonuclease analysis (REA) with three enzymes *Sma*I, *Pst*I, and *Bam*I which were used to identify 13 different genomic groups (i.e. biotypes) among 37 *Mycoplasma bovis* strains (see the Abstract). Poumarat et al disclose 37 bovis strains studied gave five different electrophoretic patterns with BamHI, four with *Sam*I and five with *Pst*I (figure 1). Poumarat et al further disclose that based

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on the combination of the different electrophoretic profiles obtained with the three enzymes, the 37 strains could be classified in 13 genomic groups (table 2).

It would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add the *Mycoplasma bovis* isolates of Poumarat et al to the vaccine composition as taught by Howard et al because Poumarat et al teach that there is a marked intraspecies genomic heterogeneity among isolates of *Mycoplasma bovis* collected from different geographic origins and that antigenic variability must be taken into account in developing diagnostic and vaccination strategies (page 319).

Applicant urges that no combination of reference including Poumarat et al with Howard et al properly establish a *prima facie* case of obviousness of the claimed invention. Applicant urges that Howard et al do not provide a vaccine protection against *M. bovis* clinical disease in general and more particularly, against *M. bovis* mastitis. Applicant urges that there is no motivation to modify the teaching of Howard et al. Applicant urges that there is no teaching within either Howard et al or Poumarat et al to modify a vaccine by inclusion of different or multiple biotypes. Applicant further urges that there is no reasonable expectation that a combination of the teachings of Howard et al and Poumarat et al would produce a vaccine against *M. bovis* clinical disease.

Applicant's arguments filed March 21, 2002 in paper No. 10 have been fully considered but are not persuasive.

It is the Examiner's position that applicant argues the references individually without clearly addressing the combination of teachings. It is the combination of all of the cited and relied upon references which make up the state of the art with respect to the claimed invention. The teachings of Howard et al have already been disclosed above. Howard et al do not teach biotypes A, B, C of *Mycoplasma bovis*. However, Poumarat et al teach biotypes of *Mycoplasma bovis*. One skilled in the art would be

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motivated to add the *Mycoplasma bovis* biotypes to the vaccine of Howard et al because Poumarat et al teach that there is antigenic variability between and among *M. bovis* isolates and this variability must be taken into account in developing diagnostic and vaccination strategies. One skilled in the art would expect that a vaccine comprising multiple biotypes of *Mycoplasma bovis* would be highly effective in providing protection against *M. bovis* infections since Poumarat et al teach that high variability exist between and among strains of *Mycoplasma bovis*. Limitations such as "protective against *Mycoplasma bovis* mastitis in a bovine species following systemic administration" are viewed as limitations of intended use. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention.

Applicant further urges that Howard (1977a), Howard (1979) and Boothby et al (1986) support the position that prior art vaccines have failed to protect against *M. bovis* disease. The Examiner agrees that the cited prior art references support the failure of vaccines comprising *M. bovis* to provide protection. However, it is the Examiner's position that the vaccine composition of Howard et al (1987) in view of Poumarat et al provides protection against *M. bovis* disease (page 376, 1st column).

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
June 11, 2002

LYNETTE R. F. SMITH
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